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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,089	09/10/2001	Todd A. Thompson	9345.17121-CON 1	1589
7590	09/19/2005			
RYAN KROMHOLZ & MANION, S.C. Post Office Box 26618 Milwaukee, WI 53226-0618				EXAMINER SMITH, RUTH S
			ART UNIT 3737	PAPER NUMBER

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/883,089	THOMPSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ruth S. Smith	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 September 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5 and 7-15 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-5 and 7-15 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/8/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5,7-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1,4,5 define the assembly as being worn on the patient and including components worn about the neck and/or back of the patient thereby including the patient as part of the claimed invention. (see claim 1, line 9). Claim 13 defines the housing in terms of the patient thereby including the patient as part of the claimed invention. The inclusion of a living being as part of the claimed invention renders the claim non-statutory.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5,7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talish et al ('070) in view of Peterson et al. Talish et al disclose a system for applying

ultrasound to the thoracic cavity of a patient comprising a housing 14,16, an ultrasound transducer positioned within the ultrasound housing 16 and an assembly including straps 20 to stabilize placement of the housing on the chest of the patient. The assembly includes a quick release mechanism as seen at the end of straps 20 in figure 1 and a quick release material as seen by the VELCRO in figure 5. As seen in figure 1, the assembly can include a halter worn about the chest and shoulders. Talish et al disclose, in column 9, that various modifications can be made to the structural configuration of the placement module. The placement module includes components that are worn about the back that leave the chest on opposing sides of the housing uncovered which would allow placement of another treatment device on the chest. Talish et al fails to specifically disclose the operating parameters of the ultrasound energy or the use of a circulating fluid. Peterson et al is just one example of many which disclose the operating parameters of the therapeutic ultrasound as set forth in claim 1. The application of ultrasound at the levels provided would inherently result in the increase of blood flow. It would have been obvious to one skilled in the art to have modified Talish et al such that the operating parameters are as taught by Peterson et al in that such are well known operating parameters for therapeutic ultrasound which will not cause harm to the patient. With respect to claim 3, the use of hook and loop fasteners are old and well known in the art as quick release mechanisms. It would have been obvious to one skilled in the art to have modified Talish et al such that the mechanism used on straps 20 is replaced with a quick release material. Such a modification merely involves the substitution of one well known type of quick release mechanism for another. With respect to claims 4,5, in the absence of any showing of criticality, the specific arrangement of the assembly to provide stabilization of the housing would have been an obvious design choice of known functional equivalents in the art, particularly in view of Talish et al disclosing that various modifications can be made to the structural configuration of the placement module. With respect to claims 7-9, it is known to use a coupling agent to couple the ultrasound into the body without attenuation caused by it passing through air. It is well known to use circulating water as this agent as seen in Peterson et al. Therefore, it would have been obvious to one

skilled in the art to have modified Talish et al such that the gel is replaced by circulating water as the coupling agent. Such a modification merely involves the substitution of one well known type of coupling agent for another. With respect to claims 10-12, Talish et al shows various arrangements for the housing which includes all of the limitations set forth. With respect to claim 13, the language set forth is directed toward intended use, however, the structure is considered to be elongated along the superior-inferior axis of the sternum.

### ***Response to Arguments***

Applicant's arguments filed 9/8/05have been fully considered but they are not persuasive. Applicant's remarks regarding the rejection under 35 USC 101 are noted, however, the claims positively set forth the assembly as being worn on the chest and therefore, the claims positively set forth part of the body as part of the claimed invention. Furthermore, claims such as 4,5,13 define structure in terms of the body and therefore include the body as part of the claimed invention. With respect to the rejection of claims under 35 USC 103, it is respectfully submitted that the application of ultrasound at the levels disclosed will inherently result in an increase of blood flow. With respect to claim 7-9, the reasoning used to modify the references to include circulating fluid need not be the same as applicant's.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S. Smith  
Primary Examiner  
Art Unit 3737

RSS